Analysis of Public Comments

Environmental Assessment and Draft Compatibility Determination for the Implementation of Wyoming Game and Fish Department's Proposed Interim Brucellosis Vaccination Program for Elk on the National Elk Refuge January 31, 2003

In total, 310 comment letters were received between the release of the environmental assessment and draft compatibility determination and the close of the comment period on January 15, 2002. 298 comment letters were received from individuals and 7 of the letters were signed by two people (i.e., a total of 305 people provided comments). Twelve letters were received from non-governmental organizations and 2 were received from Wyoming State agencies. Letters were received by email, the postal service, fax, and two were called in.

Comments from Individuals and Organizations

Of the 305 individuals commenting on the draft environmental assessment, 303 expressed opposition to the Proposed Action and the opinions of two individuals could not be accurately ascertained. The following table summarizes many of the comments of the 305 individuals that commented.

Representative Comment	Number of People
Forgo the WGFD's elk vaccination program and to concentrate instead on habitat improvements and reduce elk concentrations. A small number of people asked that elk be left alone and not crowded into feedgrounds where diseases can spread. Many characterized the vaccination program as costly and ineffective.	281
Opposed to the Proposed Action for a variety of reasons, including: • would rather see the money and effort go into a more comprehensive management plan, • the solution is not the vaccination of elk, but the vaccination/management of cattle, and • opposed to the use of "chemicals," "drugs," and other manipulations in conserving wildlife.	22
Total No. of Individuals Opposed to the Proposed Action:	303
Neutral or No Opinion Given	2
Total No. of Individuals that Commented on the Environmental Assessment	305
Other Reasons Given for Opposing the Proposed Action	
It would require the continuation of artificially feeding elk, a practice that concentrates animals at unnaturally high densities and contributes to increased disease transmission.	157
Improving habitat and natural winter forage for elk is a far more promising method of ensuring healthy elk populations and reduced spread of disease.	132
Vaccination in other areas (Greys River feedground) has shown that vaccination is ineffective.	159
The USFWS reports that Strain 19 vaccination is only 25-30% (or less) effective, provides little protection against brucellosis, and will at best have negligible effects on disease prevalence.	138
An intensive vaccination program is no way to treat our free-roaming wildlife!	89

The 3-year vaccination program would not protect livestock, citing the EA: "The interim vaccination program on the Refuge would have negligible if any short term effects on protecting livestock from the potential transmission of brucellosis from elk and bison to livestock in Jackson Hole" No documented cases of elk infecting domestic cattle with brucellosis exist under natural conditions.	34
Ranchers in Jackson Hole have successfully vaccinated their cattle against brucellosis for years, and it was livestock that originally gave the disease to wildlife.	27
Even the WGFD has called feedgrounds "A Recipe for Disaster" due to the increased likelihood of transmission of diseases such as chronic wasting disease, tuberculosis, and pasteurella pneumonia in such confined areas (Wyoming Wildlife News, March-April 2000).	12
Where migration routes are still being used by wildlife, healthy, free-ranging elk have negligible brucellosis and much higher calf/cow ratios.	31
Successful management of sustainable wildlife populations requires adequate habitat for all free ranging, healthy wildlife species.	28
Vaccination would waste thousands of dollars on an ineffective program.	33
Other Comments	
Eliminating non-native diseases like brucellosis is consistent with the NWRS mission	1
Additional comments from letters are included in the listing of comments and responses starting on the bottom of page 2 (this page).	n/a

Of the 12 non-governmental organizations, two supported the Proposed Action and 10 opposed it as shown below:

Supported the Proposed Action

Wyoming Farm Bureau

Wyoming Wildlife Federation (with strong reservations)

Opposed the Proposed Action

Humane Society of the United States

Dubois Wildlife Association

Utah Environmental Congress

Wyoming Educators for Animal Protection

National Parks Conservation Association

Defenders of Wildlife

The Fund For Animals

Animal Protection Institute

Wyoming Outdoor Council

Jackson Hole Conservation Alliance

Several letters were received that contained detailed comments. The letters, some of which contained similar comments, are summarized on pages 3-22. The entirety of the original comments was considered in preparing the responses that follow each of the paraphrased comments.

Comments from the State of Wyoming

Two letters were received from the State of Wyoming and these are addressed on pages 23-35.

General Comments

Comments

- "We recognize that the state of Wyoming is the acting management agency for wildlife species. Because of the importance of this fact, the WWF also recognizes the very real threat that exists should APHIS and the U.S. Animal Health Association end up managing wildlife populations once brucellosis, or any other wildlife infectious disease threatens the cattle industry. This is a risk that we find more potentially dangerous to wildlife and the hunter than the potential rate of infection from brucellosis on the NER. We cannot emphasize enough our concern that APHIS not become a 'wildlife manager' should the transfer of brucellosis from elk to cattle be considered a serious threat."
- 2 "The desired goal ultimately of the brucellosis topic, as was discussed in Billings, MT recently at an agency meeting generated by APHIS, is eradication of the organism from wildlife throughout the Greater Yellowstone, meaning bison and elk 'while still protecting the free- ranging herds of elk and bison.' Vaccination never eradicated brucellosis from a single fenced cattle herd until livestock protocols for test-and-slaughter were implemented. Furthermore, cattle, bison, and elk have different immune systems and strain 19 is a cattle vaccine, to which other species respond somewhat differently. Likewise, the host-organism relationship is not mimetic."
- 3 "I am well aware of why this document was prepared after the refuge position (no vaccination) was upheld in both federal district court and when appealed. In my professional experience, the decisions are always political, but if those decisions are too far removed from biological reality, either the resource will be lost, or the topic will go "back to the drawing board" with attendant waste of energy and money."
- 4 "This proposal is what I've learned to call a people-feel-good program. It will not accomplish anything worth having re. brucellosis, and if, indeed, does do more to concentrate the elk, increases the likelihood of other diseases in the elk. Tuberculosis comes to mind, which would seem to be of much greater concern. Always, there are trade-offs, and commonly the best of intentions seem to bring about an unforeseen negative in the long-term."
- 5 "In short, the Service's decision to allow the WGFD to vaccinate elk on the Refuge is the most egregious act of political prostitution I have witnessed in ten years of conservation work in Wyoming."
- "Growing scientific knowledge, some of it developed by the Service's own scientists, about the intimate relationship between habitat degradation, intensive management regimes such as feeding, and wildlife disease has been sequestered, denied, and ignored, all in the name of protecting the moribund cattle industry in and around the Greater Yellowstone Ecosystem against the nebulous risk of brucellosis infection from wildlife and stemming the livestock industry's loss of its traditional political power to control wildlife management for its own benefit."

<u>Response</u>: Comments noted. The BEMP EIS will explore many of these issues when considering long-term options for addressing disease issues for elk and bison.

Comment:

"This proposed short-term vaccination program on the refuge lacks scientific merit and as such, is nonsense. The refuge has done well in trying to get the animals less concentrated during feeding, vaccination will require as much concentration as possible and be counter-productive. Human nature being what it is, the instigation of feeding seems probable whether or not conditions merit this in a given winter. The discussion of feeding relative to successful mechanical vaccination seems to be glossed over in the generalities and assumptions. Also, once a "short-term" program is started seems likely that the long-term planning will be biased and the vaccination program will continue regardless of scientific merit..."

<u>Response</u>: Comment noted. With respect to the last sentence of the comment, please see Response to Comments 20-25.

Duration of Interim Vaccination Program

Comment:

We have some concerns that the proposed action is too restrictive in the time period that treatment for brucellosis can occur. We would encourage the federal government to automatically extend the vaccination period past the 3 year time frame outlined in the EA. We would encourage the federal government to automatically allow vaccination to continue, utilizing Strain 19 Brucellosis vaccine, until more effective vaccine is approved and allowed to be used on the NER... If the government does not extend the time period for the vaccination of elk on the NER indefinitely through this EA process, then a categorical exclusion should be utilized for future vaccination programs on the NER. We encourage the Fish and Wildlife Service to expand the Preferred Alternative to a permanent program."

Response: For the reasons set out in the EA and FONSI, the USFWS is considering whether to allow WGFD to implement interim program which would last only until the record of decision is signed for the BEMP EIS or through the winter of 2004-2005, whichever is shorter. The USFWS recognizes that the decision made in the BEMP EIS process may or may not include Strain 19 vaccination for NER elk. Additionally, there is no categorical exclusion to allow the interim vaccination program.

Comments:

9 "The WWF is concerned that the WGFD might exceed the three-year limit of this Interim Program since they stressed in the EA that vaccination must be conducted consistently over a long period of time in order for benefits to be realized (p.48) and they also stated in the EA that the seroprevalence rate on the NER would not decrease nor decline measurably with the proposed 3-year vaccination program (p.48). Extending the vaccination program beyond the three-year interim limit is not acceptable to WWF. With such poor response and results already known, it is clearly anticipated by WWF that

future efforts in management, feeding and vaccination of elk be objectively and critically evaluated in the forthcoming Bison and Elk Management Plan EIS for the National Elk Refuge."

"As proposed in the EA, this is an interim vaccination program, one lasting two or three years or until the Record of Decision (ROD) on the BEMP-EIS is signed. In fact, there is no way to determine when the ROD will be signed, leaving this "interim" plan openended. Since the EA purports to cover only a two to three year period, and the proposed vaccination program is in effect open-ended, this EA is clearly and significantly deficient"

Response: The Proposed Action has been modified slightly in the FONSI to note that the WGFD could proceed with their interim vaccination program until the ROD for the BEMP is signed, but that it cannot proceed beyond the winter of 2004-2005. We agree that a long-term vaccination program requires more comprehensive analysis, and this will occur in the BEMP EIS. See also the response to WGF Comment 32.

Level of NEPA Documentation

Comment:

"We feel the Fish and Wildlife Service could have considered brucellosis vaccination on the NER to be treated as a 'categorical exclusion' under the current NEPA rules. Categorical exclusions are allowed for those activities which do not have a significant effect on the human environment."

<u>Response</u>: The USFWS does not have a categorical exclusion to cover WGFD's proposed vaccination program.

Segmentation of NEPA Analysis

Comments:

Several letters alleged that the EA unlawfully segments a major management program from the larger elk and bison management planning process and environmental impact statement in violation of NEPA. In support of this comment, some commentors asserted that federal actions that are connected to each other (e.g., being analyzed at the same time, in the same area, cumulatively could have significant impacts, one dependent on the other) must be analyzed in the same environmental document. Separating out component parts of an EIS for independent analysis is explicitly prohibited under NEPA which specifies that an agency may not segment actions to unreasonably restrict the scope of the environmental review process. Strain 19 vaccination is connected with winter feeding in several ways, including that Strain 19 vaccination procedures depend on winter feeding, Strain 19 vaccination would not be needed if elk were not fed, Strain 19 and winter feeding could cumulatively have significant impacts, both actions are being analyzed in the BEMP EIS, the EA expires when the ROD for the BEMP EIS is signed, and issues for the vaccination EA were identified from BEMP EIS scoping.

- "Although courts have not articulated a single, rigid, set of criteria to determine the degree or permissibility of project segmentation, three general factors can be gleaned from cases addressing the problem: (1) whether the proposed segment has a substantial utility independent of future activities (*Swain v. Brinegar*, 542 F.2d 364, 369 (7th Cir. 1976) or is so intertwined with other activities that it is but an increment of a larger plan (*Sierra Club v. Stamm*, 507 F.2d 788, 791 (10th Cir. 1974)); (2) whether implementation of the action forecloses significant alternative actions (*Brinegar*, 542 F.2d at 369), and as a practical matter commitment of resources to the project tends to made further development likely (*Patterson v. Exxon*, 415 F.2d 1276, 1282 (D.Neb. 1976)); and (3) where the proposed segment is part of a larger plan, whether the plan is concrete enough to make it probable that it will be carried out in the near future (*Brinegar*, 542 F.2d at 369. Quoted from NEPA Compliance in Oil and Gas Leasing, 58 Univ. Colo. L.Rev. 677, 686 (1988))."
- NEPA regulations provide explicit guidelines on taking interim actions while an EIS is under preparation. In short, such actions can only be permitted under extremely limited circumstances (e.g., when the action is justified independently of the larger program, is accompanied by an EIS, and if the action will not prejudice the outcome of the ultimate decision on the program). Strain 19 vaccination on the NER cannot be justified independent of winter feeding, is not accompanied by an EIS, and the it's "interim" implementation prejudices the outcome of the EIS.
- Several comment letters included the following court finding in the lawsuit, *Fund for Animals v. Clark* (the lawsuit that led to the ongoing BEMP EIS process):

"If an agency is involved in several actions which, cumulatively, have a significant impact on the environment, then these actions should be considered in the same environmental document. Additionally, if agency actions are similar in that they share common timing or geography, such actions should also be addressed in the same environmental document so as to assess adequately their combined impacts. Importantly, an agency may not segment actions to unreasonably restrict the scope of the environmental review process.

In the current matter, it is undisputed that the elk feeding program, the bison feeding program and the bison management plan all take place in the same geographic area. It is equally evident from defendants' own submissions that the elk-feeding program has a profound effect on the bison herd. In fact, it is undisputed that the final recommendations in the bison management plan admit that the elk-feeding program will continue to be a factor to be considered in managing the bison. Accordingly, all three of these actions, the elk-feeding program, the bison feeding program and the bison management plan should have been considered together in the bison management plan EA so that the involved agencies could determine the combined impact of the programs [citations omitted]."

There is no compelling reason why the interim vaccination program should be implemented prior to completion of the BEMP EIS when the interim program would not

result in any measurable contribution toward addressing the stated purpose and need. The NER has implemented several programs to better address brucellosis and other disease problems, and the seroprevalence rate on the NER does not differ from state feedgrounds where Strain 19 vaccination is ongoing.

It makes no sense to expend time and money on a short-term program before the full impacts of a long-term program are evaluated as part of the larger effort to manage the Jackson elk and bison populations. As expressed by Olsen and Elzer (2002), "Therefore, it is imperative that vaccination programs be designed and managed for long-term implementation and benefits, rather than short-term gains."

Response: Comments noted. First and foremost, segmentation is concept that arises where it appears there is an attempt to avoid NEPA applicability by undertaking a smaller part of a larger project. This is obviously not the case here. The proposal to allow WGFD to vaccinate during the interim until decisions are made under the BEMP EIS process is a permissible action being taken in compliance with NEPA. The need for NEPA compliance with regard to consideration of the State's request was specifically included in the court-accepted stipulation settling litigation with the State of Wyoming, and the USFWS has prepared this EA. The agreement specifically recognized that the USFWS and NPS are in the process of preparing an EIS that evaluates the use of vaccination as a tool for the long-term management of brucellosis, and the U.S. District Court for the District of Wyoming directed the USFWS and State of Wyoming to comply with the terms of the settlement agreement. The settlement agreement requires that the USFWS make a decision based on the results of the EA, a compatibility determination, and biological assessment (independent of the decision to be made in the BEMP EIS), and that the decision will "...either be a Finding of No Significant Impact or that the impacts of the [WGFD's] proposed program are significant and require an Environmental Impact Statement."

Although we do not believe this is a segmentation issue, even if the relevant principles established by courts for considering segmentation are applied to this action, they are satisfied as well. Several courts have considered the issue, primarily in the context of State transportation projects such as highways, rail lines, and bridges where the State decides to build a discrete part of what is apparently a larger project using only State and local funding to avoid the NEPA obligations. Generally, the test that has evolved is four pronged: 1) does it have a logical terminus?; 2) does it have substantial independent utility?; 3) does it foreclose the opportunity to consider alternatives?; and 4) does it irretrievably commit federal funds for closely related projects?

The first is not particularly relevant, as it was developed primarily in reference to construction projects that had a physical beginning and end. But even so, the proposal at hand will end prior to or as a part of management decisions that will stem from the BEMP EIS. Secondly, the action has substantial independent utility in that it assists the WGFD in their management of a shared, common resource – elk – and also aids it in carrying out its responsibilities with regard to protecting livestock from disease. Again, it is independent of the larger BEMP EIS process as it stands on its own, is not a pretext

for a larger program, and does not constrain future decisions. Thirdly, it in no way forecloses the opportunity to consider other alternatives. It is for the interim only, it will not alter the current elk management program at the refuge, and it doesn't limit any of the alternatives being considered in the larger EIS. Finally, for the same reasons, it does not irretrievably commit federal funds for closely related projects. First, few, if any, federal funds will even be expended, and second, the Service will continue to manage the refuge as it has in the past, pending future decisions. This in no way locks the refuge in to continuous or long term vaccination, nor is it an automatic trigger for future decisions.

Furthermore, as noted in Chapter 2 of the EA, the decision was not to be based on whether the interim vaccination program would contribute to any elk management goals or objectives of the NER because the interim, 3-year program was not designed or intended for this purpose. The proposed action is a limited action that is independent of any federal program or plan. The USFWS is responding to an outside request to conduct an activity on the NER, and the USFWS has evaluated the proposal in this context. Given the assurances made in the FONSI (see Finding section), implementation of the interim vaccination program will not prejudice the decision to be made in the BEMP EIS or impact long-term management of the NER, nor will it impact the winter feeding program that is subject to the ongoing BEMP EIS process. The WGFD understands that implementation of the interim vaccination program for up to 3 years will not influence the USFWS's decision in the BEMP EIS process, aside from additional data provided through monitoring. The WGFD is aware that the interim program can only last as long as 3 years and that the selected alternative in the BEMP EIS process may or may not include vaccination of elk with Strain 19.

Specifically in response to the three factors identified in Comment 13 to determine whether an agency is segmenting NEPA analysis improperly, we provide the following. First, the interim vaccination program has little beneficial or adverse consequences to the NER's ongoing management actions. The interim program has little utility to the NER. This is not to say that a long-term vaccination program would not be a useful tool for disease management. The interim program, however, is inconsequential. Second, the ongoing BEMP EIS is considering a wide range of options to address disease concerns. It does not focus only on vaccination. For all practical purposes, the NER will commit very few resources to the WGFD's interim vaccination program. Finally, as stated above, the BEMP EIS is considering vaccination and other disease management tools. Allowing WGFD to implement their interim vaccination program does not commit the USFWS to favor, as a long-term solution, vaccination over other disease management options.

See also the response to Comments 20-25, below.

Pre-Decision

Comments:

Evidence that the outcome of the EA was determined before it began is disturbing. In an internal memo, a USFWS employee made reference to the Chief of the National Wildlife

Refuge System "wanting to get this through" for the Director of the USFWS and to not impact the tenuous relationship with WGFD. This email demonstrates that a political decision to approve the proposed vaccination program had already been made by high-level officials *prior to* the completion of the environmental planning process in blatant violation of NEPA's implementing regulations. The decision to remove the decision-making responsibility regarding compatibility from the NER Manager further supports the obvious conclusion that the FWS had determined to approve the project prior to completing the environmental analysis. Upon receiving the *incompatibility decision* from Refuge Manager, the Regional Director for Region 6 withdrew the manager's authority to make compatibility determinations on the WGFD's proposal.

19 After reviewing the documents we received pursuant to a FOIA request, our groups because concerned that WGFD has had tremendous influence in the decision to chose implementation of the WGFD plan as the proposed alternative. WOC and GYC understand that state agencies may certainly help provide information to federal agencies for NEPA analysis, however, in this matter there appears to have been a higher level of WGFD influence in drafting this document than is appropriate or legal.

<u>Response</u>: The internal memo (email) reflects staff to staff communications, which speculates about opinions on compatibility policy issues. They do not reflect the position of the USFWS, nor the position of the Regional Director. The USFWS reviewed all of the public comments and results of the EA, compatibility determination, and biological assessment, and the decision on this matter was made only after the review and analysis process was completed.

With respect to the Refuge Manager's authority being revoked for the compatibility determination decision, the Regional Director removed the authority to draft the compatibility determination from the Refuge Manager after a lengthy discussion and determination that there was a difference in the interpretation of the compatibility determination policy, especially in terms of assessing potential short-term and long-term impacts. The BEMP EIS that is currently being prepared and the associated compatibility determinations will address the long-term impacts of vaccination. Therefore, it was felt that the examination of such impacts need not be addressed as part of the current compatibility determination. As with any relatively new policy, such differences in interpretation are not unusual and are typically resolved during the review process. All draft public review documents were issued under the authority and perspective of the Regional Director.

Significance and Precedence Setting Nature of the Proposed Action

Comments:

In determining the significance of an action, NEPA requires agencies to consider both the context and intensity of the action. 40 C.F.R. §1508.27. The intensity of an action is measured using ten criteria. Of the ten criteria, the proposed elk vaccination project easily satisfies eight of the criteria. The criteria met or exceeded by the severity of the impact associated with the proposed action include: 1) impacts that may be both

beneficial and adverse; 2) impacts affecting unique geographic areas such as the NER; 3) the effects of the action on the quality of the human environment are highly controversial; 4) the effects on the human environment are highly uncertain or involve unique or unknown risks; 5) the action will indisputably establish a precedent for future actions with significant effects and/or represents a decision in principle about a future consideration; 6) the action is related to other actions (e.g., supplemental feeding) with cumulatively significant impacts; 7) the action may adversely affect an endangered or threatened species (see below); and, 8) the action, if implemented, will violate multiple federal laws enacted to protect the environment. 40 CFR 1508.27(b)(1,3,4,5,6,7,9,10). Given the fact that the proposed action easily satisfies 8 of the 10 intensity factors, there can be no dispute (even assuming that the proposed action was not already part and parcel of a pending EIS process) that an EIS would be required before the proposed action could even begin.

- NEPA requires that a federal agency prepare a full Environmental Impact Statement (EIS) for all major federal actions significantly affecting the quality of the human environment. 40 C.F.R. § 1502.3. In this regard, it is important to emphasize two of NEPA's inter-twined legal mandates. First, agencies cannot avoid finding an action "significant" by terming an action temporary or by breaking it down into small component parts. 40 C.F.R. § 1508.27(b)(7). Second, proposals or parts of proposals which are related to each other closely enough to be, in effect, a single course of action, shall be evaluated in a single impact statement. 40 C.F.R. § 1502.4(a). Before discussing the implications of these mandates, further background must be provided.
- Implementation of the proposed Strain 19 vaccination program may promote the continuation of feeding into the future even beyond the duration of this interim program. By moving forward with a short-term vaccination program now, the USFWS may inadvertently signal to the public and to other wildlife management agencies that vaccination and continued artificial feeding are appropriate ways to manage free roaming wildlife on public land.
- The EA "constrains the Refuge from considering disease risk in general by focusing on brucellosis alone and it fails to assess the conditions for an outbreak of a much more serious disease, such as chronic wasting disease or tuberculosis, as a consequence of continuing feeding and implementing vaccination, which absolutely requires elk to be fed."
- By moving forward with a short-term vaccination program now, the USFWS may inadvertently signal to the public and to other wildlife management agencies that intensive management techniques—such as wildlife vaccination and continued artificial feeding—are appropriate ways to manage free roaming wildlife on public land.
- The EA "fails to assess the impact of politics on the missions of the NER and the National Wildlife Refuge System."

Response: The impact analysis in the EA addressed the criteria listed in the above comments, with the exception of the extent to which the action would "indisputably establish a precedent for future actions with significant effects and/or represents a decision in principle about a future consideration." The EA identifies this as an issue. The USFWS recognizes that, once a non-USFWS program is implemented on a national wildlife refuge, it is sometimes difficult to modify or eliminate it in the future, and in this case, that it also has the potential to make it more difficult to make changes to other related programs (e.g., winter feeding). In this respect, the implementation of the interim vaccination program has the potential, if unchecked, to have influence the outcome of the BEMP EIS. However, there are several reasons why the implementation of WGFD's interim program would not ultimately have a bearing on the outcome of the BEMP EIS.

Furthermore, WGFD's proposal was not designed or intended to contribute to NER elk management goals or objectives. It is not part of a federal program. This contrasts with the role that Strain 19 vaccination would play, if it were included in the BEMP, upon the signing of the ROD for the BEMP EIS. Disease management strategies in the forthcoming bison and elk management plan for the NER and GTNP, of which Strain 19 vaccination may or may not be a part, will be aimed specifically at meeting goals of the NER and GTNP. The decision of whether to include Strain 19 vaccination (or other vaccine) in an integrated and comprehensive disease management strategy for the NER (in the BEMP EIS) will be based on decision criteria not considered in the decision identified in this FONSI. Because vaccination of NER elk (if it were to be adopted as a strategy in the BEMP EIS) would be part of a federal program to control brucellosis on the NER and to demonstrate that the USFWS will "start with a clean slate" in the BEMP EIS process, the USFWS is committed to evaluating vaccination in the context of a comprehensive and integrated disease management program. This commitment is expressed in the FONSI. Furthermore, the No Action Alternative of the BEMP EIS will not include the use of Strain 19 vaccination, as the WGFD's interim vaccination program will cease with the signing of the ROD for the BEMP EIS. WGFD expenditures for the interim program will not be a consideration as to whether Strain 19 vaccination of elk on the NER will continue as a result of the BEMP EIS process. Additional information collected through monitoring during the interim period would be considered in preparation of the BEMP EIS. In the preparation of the BEMP EIS, the USFWS and the National Park Service are working closely with the Animal and Plant Health Inspection Service, State of Wyoming, and the U.S. Forest Service on these issues.

Sound Professional Judgment – Compatibility Determination

Comment:

"Compatibility determinations must also be based upon 'sound professional judgment,' meaning that determinations must be consistent with 'sound fish and wildlife management.' Sound wildlife management logically consists of programs which benefit the target resource without significantly impacting the surrounding ecosystem..."

<u>Response</u>: Refuge managers are required to determine compatibility based on "sound professional judgment," meaning that determinations must be consistent with "sound fish

and wildlife management principles." However, in making compatibility determinations, the consideration of sound professional judgment and consistency with sound wildlife management is narrowly limited to the determination of whether a proposed use would or would not "materially interfere with or detract from the fulfillment of the mission of the System or the purposes of the refuge" (16 USC 668ee). In other words, consistency of a proposed use with sound wildlife management principles *per se* is not a prerequisite of compatibility. Therefore, even though allowing WGFD to implement a vaccination program for 2-3 years was designated as "compatible," this does not impart judgment on whether the interim vaccination program itself is consistent with sound principles of wildlife management. Because any use of long-term vaccination in the forthcoming BEMP will need to be consistent with principles of wildlife management, the use of vaccines and associated management activities on the NER will be evaluated against principles of wildlife management.

Purpose and Need Statement

Comments:

- The purpose and need statement is flawed and unsupported. The WGFD's stated purpose for the proposed action is to "increase coverage and protection of feedground elk in northwestern Wyoming." The WGFD "believes that vaccination of elk on the NER will enhance immunity and reduce the risk of transmission of brucellosis by reducing abortions caused by brucellosis." For this "purpose" to be legitimate, the USFWS/WGFD have to prove that a vaccination program on the NER will increase protection of feedground elk, enhance elk immunity, and reduce the risk of brucellosis transmission by reducing abortions. To prove the legitimacy of reducing the risk of brucellosis transmission, the agencies must disclose what the risk is and what the consequences are of such a risk. The EA fails to provide any evidence to justify the alleged "purpose" for the proposed action.
- The WGFD's alleged "need" for the action is to address the fact that "the elk overwintering on the NER maintain a relatively high prevalence of brucellosis and thus pose a risk to Wyoming's livestock industry and its brucellosis Class-Free status. DEA at 3. Furthermore, the WGFD believes that brucellosis in NER elk "poses a risk to the conservation of elk in Jackson Hole." DEA at 3. These alleged "needs" for the proposed action cannot pass even minimal scrutiny. (the letter provided detailed reasons)
- 29 "The purpose and need for the proposed action (allowing the WGFD to administer its Strain 19 brucellosis vaccine to elk on the National Elk Refuge) is not beneficial to the public's interest. The actual "purpose" as outlined in the EA appears to be predicated upon three very fragile declarations or assumptions:"
 - 1. It is predicated upon the transparent agreement between the USFWS and WGFD after the state failed to win its 1998 lawsuit against the federal USFWS to gain access to the NER to vaccinate elk. With the 2001 change of administrations in Washington, D.C., the WGFD evidently felt it could somehow overturn this decision, and was successful in 2002 in brokering a deal involving the new top level personnel in the USFWS encouraged by a Wyoming judge to vaccinate on the NER...

- 2. It is predicated upon WGFD's determination to vaccinate elk on the western Wyoming's elk feedlots. So what? Simply saying that a state agency wants to undertake an action without justification that action is without merit. And the WGFD has never adequately justified its Strain 19 elk vaccination program in any peer reviewed forum...
- 3. It is predicated upon WGFD's declaration that their Strain 19 vaccination program "enhances immunity (to brucellosis infection in elk) and reduces the risk of transmission of brucellosis by reducing abortions caused by brucellosis." This declaration does not withstand scrutiny. Independent reviews of the Strain 19 vaccination program by Texas A & M University (Adams et al. 1998), University of Idaho (Garton 1998), and Colorado State University (Burnham et al. 1998), and reviews by USFWS and USGS have determined that the WGFD's Strain 19 vaccination program is without merit...

Response: Comments noted. The reference to WGFD believing "that vaccination of elk on the NER will enhance immunity and reduce risk of transmission of brucellosis" relates to the proposal itself and not the purpose for carrying out the proposal (i.e., the action vs. the purpose for the action). With respect to the livestock-related comments on the need statement, the Department of the Interior concurs with the assessment that there is a real, albeit small, risk of elk transmitting brucellosis to livestock. Consequently, the risk of brucellosis transmission from elk to livestock poses some risk to Wyoming's Class-Free status. Furthermore, the question of whether brucellosis-infected elk pose a risk to livestock is beyond the scope of analysis of this decision-making process. Because the implementation of the interim vaccination program is inconsequential to NER management, the extent of risk of transmission is not an important factor at this time.

Similarly, the other points raised about the purpose and need statement are immaterial to the decision being made by the USFWS. As further explained in the response to Comments 12-17, the USFWS is responding to an outside request by a state agency to conduct an activity on the NER. And, in accordance with the legal settlement between the USFWS and the State of Wyoming, the USFWS has evaluated the proposal based strictly on whether the proposal would have significant environmental effects, would hinder the USFWS's ability to accomplish refuge purposes, or would detrimentally affect threatened or endangered species. In evaluating the proposal, the USFWS did not evaluate the merits of the purpose for which WGFD wishes to implement the interim vaccination program.

Range of Alternatives

Comments:

30 "The WWF is disappointed that only two options in the EA have been considered. Given the high importance the WGFD has placed on this vaccination program, the WWF would have liked to have seen additional alternatives incorporating habitat management, improvement and acquisition alternatives. WWF is concerned about brucellosis within wildlife populations and offering additional alternatives would help us to identify how this organization can contribute toward seeking a solution to this problem."

The EA does not present and analyze a full range of alternatives. The two alternatives in the EA do not constitute a reasonable range of alternatives. Other alternatives include elimination or reduction of winter feeding, immunocontraception, closing of all federal lands to cattle grazing, and improving habitat conditions to increase the winter-time distribution of elk.

Response: Comments noted. As explained in Chapter 2 of the EA, the Proposed Action is in the nature of the request for a determination of whether an action would have significant impacts on the environment or would be compatible with refuge purposes, rather than a proposal by the USFWS to address a refuge management problem. In such circumstances, the issue is whether to allow the requested activity, not to create an array of options to meet an identified refuge management need. Furthermore, analysis in Chapter 4 of the EA allows the decision maker to select either the No Action Alternative, the Proposed Action, or some action within the range of those two alternatives. The USFWS, in consultation with WGFD, believes the consideration of two alternatives is an appropriate range of alternatives given the short-term nature of an interim vaccination program and the nature of the settlement agreement.

Comment:

Since the proposal does not call for vaccination of bison – and since bison are a key player in the brucellosis issue – it's hard to understand how a piece-meal approach would be effective. I fear that such a proposal would only serve to reinforce the view by some that the aim is to clean up elk, so that bison can continue to be marginalized.

<u>Response</u>: Comment noted. The BEMP EIS will analyze the disease factors related to interactions between elk and bison. For this decision, however, such analysis was not necessary because of the short-term nature of the proposed action.

Sufficiency of Impact Analysis and Information Used – EA

Comment:

The EA does not sufficiently analyze potential impacts of the proposed action, including no analysis of cumulative impacts, an insufficient biosafety analysis, insufficient analysis of effects on threatened and endangered species, and no balancing of the limited efficacy of Strain 19 with the direct, indirect, and cumulative impacts of a vaccination program. Regarding the first point, NEPA does not contain separate regulations for short term versus long term actions.

Response: The impact analysis in the EA was based on the available information. Cumulative impacts of a long-term vaccination program will be addressed in the BEMP EIS. Because of the interim nature of the proposal and because the negligible impacts of the proposal would not contribute or add measurably to the degradation of habitat, disease risks, and other impacts caused by related programs on the NER (e.g., winter feeding), the impacts of these other programs were not detailed in the EA. The winter feeding program on the NER will continue at least until the ROD for the BEMP EIS is

signed, regardless of whether the interim vaccination program is implemented. This means that any adverse or beneficial impacts of the winter feeding program will continue through the duration of the interim vaccination program, independent of the decision to allow WGFD to implement the interim program. If the negligible impacts of the interim program are combined with the impacts of related ongoing programs, its implementation would not change the level of significance of the combined effects of related programs.

Comment:

The "significant new information" argues against allowing the vaccination program to proceed. In originally denying WGFD's request to vaccinate elk on the NER in 1997/1998, the USFWS, as noted in EA, felt that the WGFD had not adequately demonstrated the effectiveness of Strain 19 program and believed that sufficient information did not exist to show that Strain 19 was safe and effective for use on elk. Strain 19 has shown to have at best an efficacy of 25% in elk calves, which is far from efficacious. Thus, WGFD still has not adequately demonstrated the effectiveness of the Strain 19 program, the same basis for denying the request to allow a vaccination program on the NER in the first place, yet in this EA, the program is approved.

Response: While the study by Roffe et al. (2002) indicates that the efficacy of Strain 19 is low and brings to question the effectiveness of a program relying on Strain 19, it does not provide evidence that elk, other wildlife, habitat, or other resources would be harmed if a Strain 19 vaccination program were implemented on the NER. No biosafety problems were identified the study. Therefore, based on the decision criteria identified in the EA and in settlement agreement between the State of Wyoming and USFWS, the results of Roffe et al. (2002) are relevant to the decision of allowing or disallowing WGFD to proceed with their interim vaccination program in that the results support the finding of no significant effects will result from implementing the program for 3 years or less.

Comment:

The other "significant new information" is the analysis being conducted in the preparation of the BEMP EIS.

<u>Response</u>: The analysis being conducted in the preparation of the BEMP EIS was not, in the context of the settlement agreement, considered significant new information.

Comment:

- The USFWS also "failed to consider highly accurate scientific information and failed to insure professional and scientific integrity in areas including, but not limited to, the following:
 - The *lack of evidence* that livestock are at risk of contracting brucellosis from elk;
 - The success of vaccination programs to livestock;
 - The vegetative monitoring data gathered by WGFD and Bridger-Teton National Forest range habitat staff;
 - Migration and habitat information including information from the ongoing project entitled *Monitoring Distributions and Survival of the Jackson Elk Herd: 2002*

Progress Report documenting the elk migrations from the Gros Ventre to the upper Wind River and Green River drainages along similar routes to what the wildlife of Greater Yellowstone used historically."

- "...one of the most celebrated examples of 'older information' that would most definitely assist in managing elk on the NER if it was used as a prototype is a mere 15 miles north of the National Elk Refuge, at the Buffalo Valley/Spread Creek wintering complex for elk (and other wildlife) in northern Jackson Hole..."
- 38 "The EA fails to assess the WGFD's so-called 'Brucellosis Feedground, and Habitat Program' and how it has collapsed into a Feedground and Vaccination Program."

Response: All of these pieces of information are beyond the scope of analysis of the EA. As specified in the settlement agreement between the State of Wyoming and the USFWS, the USFWS was to analyze the potential environmental effects of the WGFD implementing an interim vaccination program for elk on the NER. The decision by the USFWS is whether to (1) allow the WGFD to implement their interim vaccination program on the NER, (2) not allow the WGFD to implement the interim program, or (3) conclude that an EIS is needed. Because the proposed action does not address a refuge need, and because the WGFD has not expressed an interest in implementing alternatives to the proposed action with respect to meeting the purpose and need, it would be fruitless for the USFWS to explore and then decide on an alternative that the WGFD would not implement. The WGFD is interested in whether they can or cannot vaccinate elk during the interim period prior to the signing of the ROD for the BEMP EIS. This does not mean that such alternatives, features, or information will not be considered in the BEMP EIS process.

Comment:

Pursuant to NEPA, if incomplete information relevant to reasonably foreseeable significant adverse impacts is essential to a reasoned choice among alternatives and the overall costs of obtaining it are *not* exorbitant, the agency *shall* include the information in its environmental analysis. 40 C.F.R. § 1502.22(a)(Emphasis added).

<u>Response</u>: Based on the scope of analysis delineated in the settlement agreement, no additional information was needed for the analysis.

Comments:

"The EA provides a synopsis of the extensive controversy within the scientific community surrounding the efficacy of Strain 19 at reducing the seroprevalence of feed ground elk. It is our belief that the preponderance of scientific evidence indicates that Strain 19 has very limited ability to reduce seroprevalence in feed ground elk. More importantly, it does nothing to reduce or eliminate the root cause of the high infection rate in the NER elk: the concentration of elk on winter feed grounds. In fact, in order to be implemented, the proposed vaccination program requires continued feeding."

- "The "Literature Cited" section refers to this "study" as a Greater Yellowstone Interagency Brucellosis Committee document, published by the Wyoming Game and Fish Department, and not by a peer-reviewed scientific journal. In other words, just like other documents concerning the WGFD program, the WGFD department has not submitted the Gross et. al study to scientific peer review—nor will it ever be submitted. We do know that Gross et. al's "study" is based on data submitted by the WGFD to Gross, data we already know from previous reviews to be scientifically invalid. Garbage in, garbage out. Consequently, Gross et. al's study is doubly invalid. In other words, the Service has decided to implement a program on the NER that is demonstrably scientifically invalid. This is negligence of the highest degree."
- "A particularly egregious example of the Service's negligence in addressing the scientific validity of the WGFD proposal is the Service's unquestioning acceptance of the WGFD's explanation for the spike in seroprevalence among vaccinated elk on the Grey's River feedground during the years 2000-2002. The EA at 38 states that 'this figure [supposedly demonstrating a reduction of seroprevalence on feedgrounds where vaccination occurs] does not include the last few years of data for the Grey's River feedground where there was a spike in seroprevalence related to a suspected vaccine failure.'

What 'suspected vaccine failure'? Has this been proven? Furthermore, this claim isn't logical; the alleged failure of the vaccine is irrelevant to the assessing the claims of success for the long-term program. Of all the 22 State feedgrounds, the WGFD's vaccination program has been implemented on the Grey's River feedground the longest. The WGFD's claim that the spike in seroprevalence is due to a vaccine failure begs all credulity. One doesn't need to be a trained scientist to think about the problem in this way. Given the extent and length of time of vaccination on the Grey's River feedground, the long-term protection provided by Strain 19—were the program effective—should have provided extensive protection to elk exposed to brucellosis when an abortion event occurred on the feedground. That a spike in seroprevalence occurred on the Grey's River feedground in spite of the years of vaccination lends strong support to the conclusion that the vaccination program is not effective."

<u>Response</u>: Comment noted. These factors will be considered in the BEMP EIS process. However, given the inconsequential nature of the interim program, these factors do not preclude a finding of no significant impact.

Comment:

The proposed interim vaccination program will have a significant effect on socioeconomics.

<u>Response</u>: As described in the EA, once large impacts on recreational opportunities are observed due to the vaccination program, the implementation of the vaccination program would be modified or stopped before impacts approached a level of significance. Therefore, significant socio-economic effects would not be anticipated.

Comments:

- The EA "fails to assess the ways in which WGFD program will interfere with and taint existing NER programs designed to improve habitat and reduce elk densities that increase the risk of a disease epidemic.
- The EA "fails to assess how NER programs serve as a scientific control to the vaccination 'treatment' on the WGFD feedgrounds."
- 46 "The EA fails to consider how the Refuge is the only place in the ecosystem where habitat approaches to disease control are being *consciously* implemented and monitored."

<u>Response</u>: The EA provides an assessment of how the proposed action would affect other programs on the NER in the short term. The errata sheet to the EA notes that the implementation of the interim vaccination program would eliminate a "control" (elk feeding area without vaccination) that has provided a comparison with WGFD feedgrounds where vaccination is ongoing. However, it is also recognized that many other factors differ between the NER feedgrounds and WGFD feedgrounds that limit the scientific utility of NER's use as a control area.

Sufficiency of Impact Analysis – Compatibility Determination

Comments:

- The primary standard that a refuge manager must use in making compatibility determinations is whether the proposed use will "materially interfere with or detract from the fulfillment of the System mission or the purpose(s) of the refuge." In making such determinations the refuge manager must consider not only the direct impacts of the use but also the indirect impacts, cumulative impacts of the use when conducted in conjunction with other existing or planned uses of the refuge and long-term impacts. If the information available from the proponent of a use is insufficient to document that a proposed use is compatible, then the refuge manager would be unable to make an affirmative finding of compatibility and "must not authorize or permit the use." In this case, there is no possible way that a compatibility determination can be made on the proposal because cumulative effects were not analyzed. Apparently, the Refuge Manager also felt that there was insufficient information to make a determination of compatibility.
- The compatibility determination ignores cumulative effects. Compatibility policy requires that cumulative effects be analyzed and the lack of cumulative effects analysis precludes the USFWS from making a determination of compatibility.

<u>Response</u>: As noted in the draft compatibility determination, although vaccination of elk, under current technologies, can only be effectively undertaken when elk are concentrated through a winter feeding program, implementation of the proposed use for an estimated 3 years would not have any influence on operation of the winter feeding program during this period. Therefore, although winter feeding is a prerequisite of the proposed use and

although winter feeding has resulted in adverse impacts to wildlife habitat and disease prevalence and risk on the NER, implementing the proposed use for the next 3 years would not be responsible, in whole or in part, for perpetuating these effects because (1) winter feeding would continue to be carried out for the next few years regardless of whether vaccination occurs, and (2) the proposed use would not worsen, to any measurable degree, any of the adverse effects associated with winter feeding. Please also see Response to Comment 33 with respect to cumulative impacts.

The Refuge Manager felt that, because the effects of winter feeding and other related programs were not analyzed cumulatively with the effects of the proposed action, that FWS policy did not allow him to make the determination. His interpretation of this policy differed from that of the Regional Director. As with any relatively new policy, such differences in interpretation are not unusual and are typically resolved during the review process. As a consequence of the differing opinion, the Regional Director removed the authority to draft the compatibility determination from the Refuge Manager.

Effectiveness of Strain 19

Comments:

- 49 "WWF does not consider Strain 19 vaccination to be effective with elk, as evidenced in the high seroprevalence rate of brucellosis on the state-run feedgrounds, where WGFD has been conducting a vaccination program using Strain 19 for a number of years."
- "Moreover, in a study of the efficacy of Strain 19 as a single calfhood vaccine in elk, Roffe et al. (2002) concluded that Strain 19 provided only 25 percent of vaccinated animals with protection against Brucella-induced abortion -- far from what anyone can consider efficacious. Roffe et al. (2002) also determined that their 25 percent efficacy rate was a 'maximum efficacy'" for reasons listed in Roffe et al. (2002).

Response: Comment noted.

Comment:

"The WWF encourages further study in order to find a different and more effective vaccination that would show more promising effects than that gained by Strain 19. The current seroprevalence response rate described by WGFD and in the EA is not acceptable."

Response: Comment noted.

Comment:

"The Service has given credence to the scientific validity of the WGFD vaccination program for no reason other than politics... The EA refers to the USFWS's submission of WGFD data to peer review—Smith and Roffe 1997, Adams et al. 1998, Burnham et al. 1998, and Garton 1998—but does not provide their specific findings to the public, only saying that "several reports question the validity of the results of vaccination trials conducted by WGFD... based primarily on flaws in scientific method."

Response: Beyond documenting that the design and findings of the WGFD Strain 19 vaccination trials have been found by independent peer-review to be flawed, there is little reason to go into greater detail on their findings. For the purposes of the EA, the details of their findings would merely support the main conclusion of the findings which has already been stated in the EA. Additionally, these documents are in the administrative record supporting the conclusion made in the EA.

Underlying Problem

- The underlying causes of brucellosis must be looked at and dealt with. The NER has done this and is continuing to work toward ideas to address root causes, which, I assume will be addressed in the 2005 EIS "
- 54 "Look at the root causes of the spread of disease and remedy them (habitat degradation and loss)."

Response: Comment noted.

Risk of Brucellosis to Elk

Comment:

Brucellosis is not an ecological problem for elk and does not jeopardize the Jackson elk herd. The Jackson elk herd is above objective despite the high prevalence of brucellosis. The transmission of multiple diseases, such as chronic wasting disease and tubercullosis, are of more importance.

<u>Response</u>: Comment noted. This is consistent with the perspective of the USFWS and what is said in the EA.

"It's difficult to understand the sense of urgency for implementing an interim plan for 3 years, when brucellosis has been chronic in the state's elk for some time."

Response: Comment noted.

Transmission Risk from Elk to Livestock

Comments:

57 We take exception with WGFD's statement that the relatively high prevalence of brucellosis, 'poses a risk to Wyoming's livestock industry and its brucellosis Class-Free status' and, that 'it also poses a risk to the conservation of elk in Jackson Hole. First, many ranchers in the area vaccinate their most susceptible cattle... Second, with the current temporal and spatial separation of cattle from elk in the spring and early summer, additional protection is provided to local cattle herds. Third, the numbers themselves demonstrate that the incidence of infections in regional cattle herds has been extremely rare and decreasing with every year...

- Of course to reduce a risk -- a risk must exist. While the agencies regurgitate statements alleging the risk of brucellosis transmission, they have never quantified this risk. Obviously, cattle are the species primarily at risk from a brucellosis outbreak. However, cattle and feedground elk have intermingled on the NER and adjacent lands for decades without any documented or verifiable interspecific transmission event. This is partially explained by spatial and temporal differences in range use by cattle and elk, the birthing behavior of elk, the remote risk of a transmission event, and because local ranchers all vaccinate their cattle against brucellosis.
- 59 Even with a high prevalence of brucellosis, there is no evidence that cattle are at risk.
- "Our wildlife management should not be dictated by the fears of the livestock industry...

 The WGF is being pushed to once again ask for the right to vaccinate the elk on the refuge so as they can continue with their goals to manage for the eradication of brucellosis in Wyoming. There is also pressure from the GYIBC..."

Response: Comments noted. Please see response to Comments 27-29.

Priority Public Uses of Refuges

Comment:

The USFWS should deny the use because it conflicts with priority public uses of the NER, as stated in the EA and draft compatibility determination.

<u>Response</u>: Although implementation of the WGFD's proposed interim vaccination program may have adverse effects on wildlife-dependent recreational opportunities, any effects are anticipated to be negligible to minor. This level of impact does not automatically trigger a decision to deny a use.

Conflicts with Preparation of the BEMP EIS

Comment:

- The USFWS should deny the use because it significantly interferes with the BEMP EIS. The preparation of the EA is taking time away from the preparation of the BEMP EIS. It will delay the completion of the refuge's comprehensive conservation plan. Allowing WGFD to vaccinate elk on the NER under the proposed action will have an impact on the outcome of the BEMP EIS. Implementation of the proposed action will seriously undermine the BEMP EIS process and public trust in the process.
- The EA "fails to assess how implementing the program interferes and forestalls the ongoing Bison/Elk EIS process as well as how it interferes with the long term comprehensive conservation planning for the NER required for all refuges by the National Wildlife Refuge System Improvement Act of 1997."

<u>Response</u>: Comment noted. The USFWS acknowledges that the preparation of the EA, compatibility determination, and biological assessment has delayed the completion of the

BEMP EIS for a short time. See Response to Comments 20-25 with respect to the implementation of the proposal having an impact on the outcome of the BEMP EIS (e.g., by influencing its outcome).

Comment:

Given the legal and scientific inadequacies inherent in the EA, the best resolution of this issue would be for the USFWS to rescind the EA in its entirety and resume work on the Jackson Bison and Elk EIS. If that option is unappealing to the FWS, then it must conclude that the impacts associated with the "interim" elk vaccination project are so significant that an EIS is required.

Response: Comment noted.

Budgetary Considerations

Comment:

65 "In light of the current tough economic times agencies are experiencing, the WGFD should be more economically considerate in evaluating the cost-benefit of vaccinating elk with a vaccine that has been found to be less effective with elk than originally thought."

<u>Response</u>: Comment noted. This issue appears to be an issue that would influence the decision of the WGFD rather than an issue for the USFWS.

Comment:

"After considering a comparison of the costs versus the benefits of this proposal, one finds the program to be a misuse of public funds. WGFD proposes to spend about \$2100 each year on a program that admittedly will have "negligible effects" on the elk herd. See EA at 40. This would be in addition to the ten thousands of dollars that have been spent cumulatively on vaccinating elk to eradicate brucellosis and fails to take into account the cost of the EA and the CD."

<u>Response</u>: Analyzing costs and benefits associated with the use of state funds to administer a state-run program is beyond the scope of the EA analysis. The use of state funds is an issue for the WGFD, not for the USFWS.

NER Actions to Reduce Brucellosis

Comment:

67 "The WWF recognizes the successful efforts made by the NER in reducing brucellosis on the refuge by implementing new feeding programs over the years. These new feeding programs have decreased elk concentration during feeding and decreased human-elk interactions. There exist concerns that the implementation of the vaccination program would yet again concentrate numbers of elk and increase potential for infection, in addition to placing a stress on these animals."

Response: Comment noted.

Responses to Comments from the Wyoming Game and Fish Department

WGF Comment 1:

In general, we are disappointed by the negative tone of the Environmental Assessment (EA), which expresses a lack of objectivity and the anti-Strain 19 vaccination bias of the U.S. Fish and Wildlife Service (USFWS).

Response: Comment noted. We disagree with this characterization of the EA.

WGF Comment 2:

The EA states "the USFWS and the State of Wyoming agreed that significant new information exists for the Defendants (USFWS) to consider in determining whether to allow the Plaintiffs (State of Wyoming) to vaccinate elk on the National Elk Refuge (NER)." However, the EA does not do a very good job of identifying new information which includes the Roffe Strain 19 elk vaccination study which demonstrated efficacy, continued declining seroprevalence for brucellosis on state feedgrounds due to the Strain 19 vaccination program, and increased experience by the Game and Fish Department at ballistically vaccinating elk since elk were last vaccinated on the NER.

Response:

- The results of the study conducted by Dr. Thomas Roffe and others is described in the EA.
 Without specifics as to why the EA did not do a good job in of identifying new information
 (e.g., what additional new information was left out?), there is no way to determine whether any changes are needed.
- A reference was made to the reduction of brucellosis seroprevalence on selected WGFD feedgrounds (information provided by WGFD), but because the proposed action is a shortterm, interim program, there was no need to go into extensive discussion about long-term effects of using Strain 19. Similar reductions have been observed on the NER in absence of vaccination.
- WGFD had not, until these comments, mentioned their increased experience at ballistically
 vaccinating elk since elk were last vaccinated on the NER (no comments were received on
 previous drafts of the EA reviewed by WGFD).

Specific comments follow:

WGF Comment 3:

<u>Chapter 1, pages 6-7:</u> For elk, additional benefits include not only reduced prevalence of the disease but also reduced prevalence of hygromas, synovitis, arthritis, and consequent predation. Reduced probability of transmission to other species (bighorn sheep, moose) should be considered a benefit. Failure to achieve a target should not be considered as a negative, in the face of decreased prevalence.

Response: This is the first time that WGFD has identified these items as issues to consider in the EA. They were not added as issue statements. Nonetheless, the topic in the first sentence was addressed in Chapter 4 of the EA. Data on moose in the southern GYA (T. Roffe, USGS, BRD, pers. comm. 2003) do not support the contention that brucellosis has any impact on that species and, thus, there may be no defined benefit to that species. Data on brucellosis in bighorn

sheep does not appear to be available. Regarding the last sentence, the failure to achieve the target was not stated as a negative. It was merely stated as an issue on page 7 of the EA.

WGF Comment 4:

<u>Chapter 2, page 9:</u> Getting elk off feed earlier would help, since abortions begin in February and peak in April, but delaying feeding until January would have no effect.

Response: Comment noted, and this has been noted in errata sheet for the EA.

WGF Comment 5:

Chapter 2, Proposed Action Alternative in the Acclimation section, page 12: We strongly disagree with starting the acclimation after elk have become accustomed to normal operations. Acclimation activities should start with the onset of feeding so elk associate the snow-cat vehicles (used to vaccinate) with the feeding operation. Starting acclimation after the onset will only delay or increase the time taken to begin vaccination. We see no valid reason not to allow acclimation to start during the onset of feeding. USFWS personnel have told our personnel that their concern comes from the elk feeders, but were not specific. Our acclimation process is as follows: 1) allow elk to become comfortable with the whole feeding operation and snow-cat vehicles before ever sounding off any vaccination equipment (guns), 2) gradually acclimate elk to the noise of the vaccination guns, and 3) continue acclimation until elk become comfortable with snow-cat vehicles, noise, guns, etc. associated with vaccination activities.

Response: As a compromise between a 1-week delay between the initiation of feeding and the initiation of acclimation activities (as NER feeders would like to see) and having feeding and acclimation activities initiated at the same time (as several WGFD staff advocated), Tom Thorne, WGFD had suggested in the October 10, 2002 meeting to not identify a set number of days from the initiation of feeding until acclimation activities begin and to leave this flexible. This was agreed to in the meeting and text was revised to delete references to numbers of days.

WGF Comment 6:

<u>Chapter 3, page 21:</u> It should be noted that other ungulates don't use feedlines, but may share other habitat.

Response: Comment noted. This was noted in the errata sheet for the EA, although other ungulates, such as bison, do use feedlines.

WGF Comment 7:

<u>Chapter 3, page 26:</u> Fishing is allowed only from August 1-October 31, when elk are absent.

Response: This is correct.

WGF Comment 8:

<u>Chapter 3, page 27:</u> It should be noted that vaccination may prevent cattle abortions but will not prevent seroconversion. Seroconversions will be expensive to producers and the state (requires further testing and trace-backs).

Response: Comment noted.

WGF Comment 9:

<u>Chapter 4, page 33:</u> What is the probability of the effects being negligible, minor, moderate or major? We believe most effects listed as major have very low probability of happening. It is very unlikely that for elk moving away from a particular feeding area, aggression resulting in severe injury or death will occur. No moderate or major effects have occurred with vaccination on state feedgrounds.

Response: The major effects in question were noted as possibly being an occasional, short-duration occurrence. However, the text also noted that action would be taken to ensure that it does not happen repeatedly. There is little information to determine the probability of effects being major and this is why a range of possible responses was identified and why the text specifies that corrective actions would be taken if major effects do occur. As noted in the EA, while there are many similarities between State feedgrounds and NER feedgrounds, there are many differences as well.

WGF Comment 10:

<u>Chapter 4, pages 34-38:</u> We are glad to see Strain 19 research from both Tom Roffe and Tom Thorne mentioned in this document. We reiterate our concern about the negative tone associated with the use and efficacy of Strain 19 vaccine, along with a biased interpretation of WGFD's data and research by USGS personnel.

Response: The results of both sets of studies were presented objectively in the text. Following this presentation of the studies and their results, it was noted that four sets of reviewers, including three sets of independent reviewers from universities, found the WGFD clinical trials to have substantial flaws in scientific method. Therefore, favoring the Roffe et al. (2002) study and pointing out flaws in WGFD clinical trials was done without bias. The results of the independent reviews, which are on file at the NER headquarters, needed to be considered in the environmental assessment. Nonetheless, in an attempt to recognize both sets of studies, we used 25-30% efficacy in many places in the EA.

It's not clear where there is undue "negative" tone with respect to Strain 19. There is no dispute that the clinical efficacy of Strain 19 is low (somewhere in the neighborhood of 25-30%). In the comment letter from the Wyoming Livestock Board, Jim Logan noted that Strain 19 is "somewhere between 10 and 30 percent efficacious" (WLB Comment 4). While it is recognized that efficacy of Strain 19 in field conditions would not be exactly 25%, the use of controlled clinical trial data is the best available estimation of efficacy.

WGF Comment 11:

In regards to efficacy of Strain 19 vaccination, we do agree that during the interim period (approximately 3 years), changes in seroprevalence would not be measurable, although we are disappointed that the USFWS didn't attempt to project long-term benefits associated with the use of vaccination. There are only two sentences in this entire section that mention potential long-term benefits associated with vaccination, which is then followed by a sentence that essentially questions if the changes in seroprevalence are even due to vaccination. The WGFD has been collecting feedground serology data since the early 70's and has been implementing Strain 19 vaccination since 1985. The WGFD essentially has collected all the field serology data. Our feedground seroprevalence data for all feedgrounds show a 46% decline [35% (n=744/2137) to 19% (n=158/854)] since implementing Strain 19 vaccination for the past 18 years. The USFWS is aware of and has been provided all of this data, but has elected to use little of the information in the EA document.

Response: There was no need to project long-term benefits associated with the use of vaccination because the proposed action is anticipated to only last 3 years. Because of the interim nature of the proposed vaccination program, long-term benefits are immaterial. Nonetheless, at the request of WGFD (and as provided by WGFD) during the preparation of the EA, information was presented in the EA that compared seroprevalence of brucellosis in elk on 6 of the WGFD feedgrounds prior to the initiation of vaccination and seroprevalence on these same feedgrounds following the implementation of their Strain 19 vaccination program. Because long-term vaccination of elk on the NER is being evaluated in the BEMP EIS, and given the high level of interest expressed in public comments about the results of vaccination on WGFD feedgrounds, the USFWS welcomes any additional information and data sets related to long-term changes in seroprevalence on all WGFD feedgrounds where serology data has been collected.

WGF Comment 12:

<u>Chapter 4, No Action Alternative, pages 34-35:</u> We disagree with this paragraph. Although the Department is concerned about brucellosis transmission from elk to cattle, our primary concern is about reducing, and eventually eliminating, transmission from elk to elk. Brucellosis is a serious disease of elk, and reducing elk to elk transmission is the only way the disease will ever be eliminated from elk. We believe brucellosis is a serious problem ecologically, to elk, and we are not convinced brucellosis is less serious ecologically, or less pathogenic, than other diseases.

Response: Comment noted. The paragraph was not intended to portray the WGFD's perspective.

WGF Comment 13:

Chapter 4, Proposed Action, 2nd paragraph, page 35: The EA fails to point out that approximately 95% of the non-vaccinated control elk in the Roffe et al. (2002) study aborted, which indicates the challenge dose used in that study was excessive and, therefore, demonstrated less efficacy for Strain 19 vaccine than would occur under natural conditions. The abortion rate in non-vaccinated, naturally infected elk is approximately 54% (Thorne et al. 1978), not 95%. Thus, if the abortion rate in the Roffe et al. (2002) study was corrected for what happens under natural infection, rather than artificial overwhelming infection, the Strain 19 efficacy rate would have been greater than 25%. In controlled Strain 19 vaccination trials, the abortion rate of non-vaccinated, artificially infected elk has considerably exceeded the abortion rate of naturally infected, non-vaccinated elk, indicating most infectious doses under field conditions are less than 4.5-7.5x10⁶ (Thorne et al. 1981, Herriges et al. 1989) and 1x10⁷ cfu (Roffe et al. 2002) used in controlled vaccine trials.

Response: Similar comments, provided to the USFWS by the WGFD on a draft of the EA, were considered prior to the completion of the EA. The comment confuses clinical trial abortion in control animals with field abortion rates. The two are not comparable. A controlled clinical trial uses a single dose, delivered to every animal in the same manner so as to eliminate variation within the experiment. On the other hand, natural field abortion is a summation response to a variety of factors, including *Brucella* exposure, *Brucella* dose, nutrition, age, stage of gestation, history of previous exposure, environmental variables, and repeat exposure and dosing. The abortion rate in first-time *Brucella* exposed elk on the NER is unknown. The goal in a clinical experiment is to maximize response in control animals without overwhelming the immune system while using a challenge that is within the realm of "normal" or "possible" so as to optimize the measured effect of vaccination. ALL animals in such a trial are exposed and receive this exact same dose so that the only variable is "treatment" (i.e., the only difference is that one group is vaccinated and the other is not). Lower doses of the challenge effectively decrease sample size

(control animals that do not abort in response to challenge are simply a measure of innate resistance and have no relevance to protection afforded by vaccination). Therefore, by lowering the dose of the challenge in an experiment, the percent of animals that do not abort could increase, but the measured efficacy may not necessarily change (although the sensitivity of the experiment could decline). Whether vaccine performance will improve under different challenges is unknown and would need further investigation. Such a set of trials might include a variety of challenge doses, each with a matched set of vaccinates and controls, to calculate a range of efficacy.

Additionally, Thorne et al (1978) is not an assessment of first-time-exposed, naturally infected elk. The study examined transmission between elk artificially inoculated with B. abortus strain 2308 and serologically negative elk from a chronically exposed herd. The dose for challenge was selected based purely on serologic responses in 4 elk and was considerably less than what is used in current challenge experiments. This dose may have been an underdose as evidenced by only 7 of 16 inoculated elk aborting. It is possible that a different challenge dose administered to these "originally-infected" elk could potentially have altered the "natural" dose of Brucella received by the naturally-infected group of 13 elk and, thus, it could have affected the number of abortions these elk had (7 of the 13 cows aborted; or 54%). Furthermore, the authors noted that "these rates of abortion are minimal" because of the stingent criteria they used to assign brucellosis-induced abortion and because the authors "suspected several aborted fetuses were never located, and if this was the case, the rate of abortion might have been higher." The authors also acknowledged the presence of latent infections, which may affect abortion rates. Additionally, most (but not all) of the elk in the study were trapped wild on the NER and, therefore, there would have been no way of knowing the percentage of these animals that had actually been exposed (which can't be definitively ascertained through testing). Later data clearly demonstrated serologically negative NER elk harboring Brucella. Therefore, how data from this study might apply to first-time-exposed elk in the chronically infected herd of the NER is unknown.

WGF Comment 14:

<u>Chapter 4, Brucellosis, Proposed Action, 3rd paragraph, page 35:</u> the challenge dose used by WGFD was 7.5 x 10⁶ cfu (Thorne et al. 1978, 1981; Herriges et al. 1989), which should be corrected in two places. This may be our error and we apologize.

Resonse: This has been noted in the errata sheet for the EA.

WGF Comment 15:

Chapter 4, Brucellosis, Proposed Action, 5th paragraph, pages 35-36: We do not know what the Roffe et al. (2002) "real world" conditions are, but our 30+ years of research under controlled and field condition have provided an extensive understanding of "real world" conditions. This paragraph is clearly biased to imply that vaccine efficacy is most likely to be less than determined under controlled trials when, in fact, it is most likely to be greater under field conditions. Most epidemiologist argue that brucellosis vaccines (and others) yield better results in the field than in clinical trials due to herd immunity and the lower challenge dose received by many animals in the field. Certainly, we don't believe that 60-95% of elk exposed in the field abort (otherwise the calf loss would be much higher). Field protection is also enhanced because when one animal that normally would have aborted fails to do so, it is no longer a source of infection to other animals. If this paragraph cannot be balanced, it should be deleted.

Response: Several of these comments were considered prior to the completion of the EA. While we appreciate that WGFD has extensive experience in controlled and field situations, the proper comparison to make with a clinical trial is how well vaccine (and vaccine alone) protects

an animal from a challenge of a pathogenic agent. In the natural environment, exposure and challenge dose range from nothing to billions of organisms. Secondary effects (e.g. such as reduction in abortion having a compound effect by not exposing other animals) may or may not occur. Additive or synergistic effects of habitat improvement, climate variation, feeding regimen, dispersal, etc may or may not occur. The abortion rate on NER has not been rigorously measured and we don't know what threshold might have to be reached to decrease transmissions. Management effect (i.e. change in seroprevalence or infection within the herd) is a product of all actions imposed on that population, of which vaccination is only one.

While most epidemiologists may argue that brucellosis vaccines yield better results in the field, these apply to vaccinating livestock as used in intensive herd management plans. There are many differences between the result of herd management actions and clinically-measured efficacy of a vaccine in wild, free-ranging elk.

The reference to "real world" in the EA was specifically with reference to vaccine efficacy and not to the ultimate management effect. There are several factors in the "real world" that can directly affect the efficacy of a vaccine: (1) In the field, the actual successful delivery of vaccine will always be either equal to or less than that delivered in clinical trials. (2) Ballistically delivered vaccine may produce a poorer cell-mediated immune response compared to hand delivery used in clinical trials (Steve Olsen USDA, ARS pers comm), (3) Controlled experimental trials (specifically Roffe, et al. 2002) use freshly prepared, directly injected vaccine, as compared to stored and lyophilized vaccines contained in biobullets. This may result in a lower number of colony-forming units than the number in freshly constituted vaccine as WGFD found for vaccine delivered in 1998. In addition, elk in clinical trials of Roffe et al. (2002) were raised from calves in captivity, were fed ad libitum food and supplementation, and had diminished winter stress compared to wild, free-ranging animals. The comparison is only meant to infer that the per dose vaccine efficacy in the clinical trial likely optimizes vaccine effect. We believe this is a correct inference.

WGF Comment 16:

Note that Strain 19 is considered to have played a major role in the elimination of brucellosis in U.S. cattle herds, yet its efficacy in clinical trials is very similar to that seen in elk trials.

Response: While Strain 19 may have played a role in the elimination of brucellosis in U.S. cattle herds, the extent to which it contributed to the elimination of brucellosis in these herds is unknown. The role that Strain 19 played cannot be separated from the many confounding and possibly synergistic management actions that were undertaken. Cattle were intensively managed, with management actions including removal of likely infected animals, age and sex segregation, multiple testing in short time intervals, segregation of high risk negative animals, as well as the use of vaccines. Elk in a wild setting cannot be managed at the same intensity. Also, the vaccine efficacy reported by USDA is higher in cattle than has been measured in elk. These results are based on challenge studies conducted using similar protocol as were used in Roffe et al. (2002), which found an efficacy in calfhood elk of 25%.

WGF Comment 17:

The citation regarding cfu's in infected material should be Alexander et al. 1981, and Thorne (2001) should not be cited because that is not the primary citation. The sentence attributed to Roffe (pers. comm. 2002) should be elaborated on or substituted with verbiage similar to that suggested above for the 2^{nd} paragraph.

Response: This has been noted in the FONSI. Regarding the reference to Roffe (pers. comm. 2002), Dr. Thomas Roffe felt the statement was fine as it is, except that "decline" should be replaced with "change" in recognition that the level of protection provided as the challenge dose

increases may not necessarily decline in all situations.

WGF Comment 18:

<u>Chapter 4, page 37:</u> The calculations, which estimate that 20% of calves and 9-11% of cows will be protected by vaccination, are flawed due to the unsubstantiated assumptions that field protection will be 25%.

Response: As in all models, calculations are based on the best available information and assumptions. The information and assumptions upon which the calculations were based are clearly spelled out in the EA. If there is reason to believe that field efficacy is markedly different than 25%, then the calculations would have to be adjusted accordingly. However, based on the results of Roffe et al. (2002), which is the best available information, we modeled the effect of a 25% efficacy of Strain 19 in our calculations. No information has been provided on the field efficacy of Strain 19 or on how exactly field efficacy would differ from efficacy measured in clinical trials. The efficacy of Strain 19 would need to be considerably higher in order for the percent of animals protected to increase markedly, especially in cow elk. Models of the effect of brucellosis vaccination on disease prevalence (e.g. Peterson et al. 1991) fail to show significant overall management effect with low vaccine efficacy (e.g., 24%). See also Response to WGF Comments 13 and 15.

WGF Comment 19:

<u>Chapter 4, Proposed Action, Biosafety, 1st paragraph, page 38:</u> Because no adverse effects of Strain 19 as used with elk of feedgrounds has been reported, the last sentence should be reworded: "No adverse effects of Strain 19 on feedground elk, where administered at doses used by WGFD, has been documented."

Response: This has been noted in the FONSI.

WGF Comment 20:

Seroprevalence (using the "standard" tests) may actually increase in the short term while adults are being vaccinated.

Response: Comment noted.

WGF Comment 21:

We believe the positive effect of vaccination will be minor to moderate, certainly not "negligible". It is true that a longer-term program would be expected to yield greater benefits.

Response: This conflicts with the statement on page 3 of this letter (WGF Comment 11), where it is stated that "...we do agree that during the interim period (approximately 3 years), changes in seroprevalence *would not be measurable*," emphasis added. Of the terms used in Chapter 4 that are listed and defined on page 31 of the EA, having "no measurable effect" is most similar to the definition of "negligible" (i.e., the effect is at the lower level of detection). For effects to be minor, a monitoring program would have to be able to detect the change.

WGF Comment 22:

<u>Chapter 4, page 39:</u> Again, using 25% efficacy to determine impacts on the population is flawed. We do agree that the impacts will be negligible to minor. The reduction in brucellosis-related lameness (and resulting predation loss) will also increase the population (though probably by negligible to minor levels).

Response: As noted in WGF Comment 18, the extent to which 25% efficacy is inaccurate, the modeled effects would be different. However, at present, there is no better estimate of efficacy of Strain 19. It should also be noted that the calculations assume that 100% of the female elk on the NER would be vaccinated by the third year. This obviously is an overestimate given the lower objectives of the proposed action and the potential for not achieving these objectives. There are no estimates on the extent to which reductions in brucellosis-related lameness would result in reductions in predation, but if brucellosis-induced lameness affects predation rates, they likely would be negligible to minor as noted in the comment. We are unaware of any studies that would provide information on approximate proportions of seropositive elk that exhibit brucellosis-induced lameness.

WGF Comment 23:

<u>Chapter 4, page 40, the Box explanation of calf recruitment and elsewhere:</u> Although we agree that any increase in elk recruitment would be negligible during the period of the interim vaccination program, we question the convoluted efforts to calculate recruitment and doubt it has any validity. As an example, the calculations in the box would not be valid if Oldemeyer et al. (1993) and Roffe et al. (2002) used different abortion rates for non-vaccinated elk.

Response: Each of the figures used in the estimates are based on research results and these are cited. To the extent that the research results are in error, the estimates resulting from the calculations in the text box on page 40 of the EA would be in error. Therefore, as the above comment points out, if the abortion rates identified by Oldemeyer et al. (1993) are incorrect or if the efficacy determined by Roffe et al. (2002) is markedly different than what occurs in a field setting, then the estimates would be off somewhat. However, no evidence has been provided that the estimates of Oldemeyer et al. (1993) are in error. While recognizing that the 25% efficacy of Strain 19 in calfhood elk was measured clinically and that efficacy in a field situation may be different (see Response to WGF Comment 13), no better estimates are available at this time. Furthermore, even if efficacy in the field is actually higher than what was determined by Roffe et al. (2002), for example if efficacy was actually 40%, the estimated increase in calf production would be 16 rather than 10. When more than 2,500 calves are born in a given year, the possible discrepancy makes little difference in quantifying the effects on calf production. Conversely, if fewer than 100% of the female elk were vaccinated by the third year, the increase in calf production due to vaccination would be proportionally lower.

WGF Comment 24:

<u>Chapter 4, page 42:</u> For the Effects due to Changes, again no mention is made of reduced predation due to reduced lameness. Also, under Biosafety, the no-action alternative should mention that field strain *B. abortus* can negatively affect other species of wildlife (moose and bighorn sheep). Vaccination may prevent disease/death in these species.

Response: These issues had not been brought up as an issue by WGFD during the preparation of the EA. They have been noted in errata sheet for the EA. However, given the negligible effects that the interim program would have on prevalence of *B. abortus* in elk, there would be negligible or no changes in the risk to other species. Furthermore, based on sampling conducted to date, there is no evidence that moose in the Jackson area have ever been infected with brucellosis. See also response to WGF Comment 3.

WGF Comment 25:

<u>Chapter 4, page 43:</u> The majority of vaccinated elk are expected to have cleared the vaccine prior to migration off the NER. Therefore scavengers, predators, and other wildlife found off the NER will have little change for exposure to Strain 19 from elk tissues.

Response: This has been noted in errata sheet for the EA, although we are unaware of any data definitively showing this response.

WGF Comment 26:

<u>Chapter 4, page 44:</u> Under Biological Diversity, domestic animal and human vaccination also introduce exotic strains of bacteria and viruses to the Greater Yellowstone area.

Response: Comment noted.

WGF Comment 27:

Chapter 4, page 45: Do sleighs approach elk while they are on the feed lines?

Response: Yes, this happens on occasion when elk linger on the Nowlin feedground. However, on most mornings, elk have dispersed from feed lines before the sleigh rides being operating.

WGF Comment 28:

<u>Chapter 4, page 46:</u> We disagree that the interim vaccination "would have negligible, if any short term effects on protecting livestock...". Changes in seroprevalence in the short term is irrelevant. There would be an immediate reduction in abortions by cow elk. If the interim vaccination program prevents the single abortion that would have led to a bovine infection, the positive effects would be major. Once again, the negative bias of the authors is apparent.

Response: Yes, there may be a reduction in abortions by cow elk, as indicated in the EA (pages 39 and 46). It is agreed also that, if the interim vaccination program prevents the single abortion that would have led to a bovine infection, the positive effects would be major. However, the probability of a bovine being infected by an aborted elk fetus during the next 3 years, absent the interim vaccination program, is extremely low. With the implementation of the interim vaccination program, the probability would still be extremely low and the change in risk would not be measurable. As explained in the EA (page 46), most of the abortions by elk occur in locations and at times when livestock are not present. A small change to an already very low risk cannot be considered a major effect.

WGF Comment 29:

For human health, reducing infection in elk will reduce the already small risk of a person contracting brucellosis from an elk or from livestock that obtained the disease from elk. The risk to the vaccination team is essentially nonexistent. Even if exposure occurred, treatment would be sought and pre-emptive treatment is very effective.

Response: Comment noted. The EA noted that there was a negligible to minor potential of the vaccination team becoming infected. Based on the above comment, it would be more accurate to delete "to minor" from the statement.

COMPATIBILITY DETERMINATION

WGF Comment 30:

We disagree with the 5th paragraph on page a-5, Anticipated Impacts of the Use, Elk Population, Effects of Brucellosis in Elk. Brucellosis is a problem biologically; better references than Smith and Robbins (1994) could have been used. It is completely inappropriate to deny that reducing seroprevalence of brucellosis (which is clearly compatible with the mission of the

NWRS) contributes to the mission because vaccination does not address other diseases that are for the most part insignificant or non-existent. The proposed action is specific to brucellosis.

Response: The statement in the draft compatibility determination addressing the NWRS mission appears to have been misstated and has been revised in the final compatibility determination. Reductions in seroprevalence of brucellosis in elk on the NER, in and of itself, would contribute to the NWRS mission. The intent of the statement was to clarify the importance of controlling brucellosis relative to addressing other, more biologically significant diseases should they be introduced into the population (e.g., chronic wasting disease, bovine tuberculosis). Given the relatively low biological significance of brucellosis to elk inhabiting the NER and the potentially devastating consequences of other infectious diseases, reducing the seroprevalence on the NER to some unknown level without addressing the underlying factors that allow brucellosis to flourish is a much lower contribution to the NWRS mission than taking action that would address these factors and reduce the spread of infectious diseases, including brucellosis.

WGF Comment 31:

It should be noted in the last paragraph on page A-6, that by addressing only calves, the compatibility determination fails to recognize that the WGFD proposal includes adult cow elk.

Response: The paragraph addresses both calves and cows.

WGF Comment 32:

We suggest two other changes to the Compatibility Determination. The first is to provide that the interim program will continue until the Bison and Elk Management Plan (BEMP) is issued. Presently, the document states it will only continue until the 2004-05 season. Recognizing that 2005 is the current date for release of the EIS for the BEMP, it is quite possible that the deadline for the BEMP could be extended. If so, the interim program should be allowed to continue until the BEMP is finalized. This change should also be made in the text of the EA.

Response: Based on public comment, the anticipated signing of the ROD in February of 2005, and the analysis being based on a 2-3 year program, the compatibility determination and the EA have been modified to clarify that the interim vaccination program could proceed until the ROD is signed, but that it could not extend beyond the 2004-2005 season. If the ROD includes Strain 19 vaccination in the selected alternative, this deadline would account for a delay in the signing of the ROD for up to nearly one year without any break in the vaccination program.

WGF Comment 33:

Secondly, we would like to see some discussion in the document, probably in the Justification section, that emphasizes the USFWS's obligation under the National Wildlife Refuge System Improvement Act to implement State management strategies on federal public lands to the maximum extent possible, especially where such management bears directly upon the well-being of state interest arising outside those public lands. The Tenth Circuit has opined as much, and stated that conflict pre-emption principles apply. The discussion should reference to 50 CFR 26.41(a)(6)(i) which states Compatibility Determinations will include information regarding "The nature and extent of the use including the following: Is the use a priority public use?" The USFWS should reference that the importance of the issue to the State's wildlife management and livestock interests makes it a priority public use, in addition to the other compatibility elements. That would further strengthen the conclusion and also include some of the 10th Circuit reasoning.

Response: According to the NWRS Improvement Act, 50 CFR 26.41, and USFWS policy, the requirement to coordinate and cooperate with the state in managing refuges is not a criterion in determining whether a proposed used is compatible. To allow state-sponsored programs to be implemented on national wildlife refuges, the programs must be consistent with and cannot detract from the NWRS mission and refuge purposes. According to USFWS policy, "The justification must provide a logical explanation describing how the proposed use would, or would not, materially interfere with or detract from the fulfillment of the National Wildlife Refuge System mission or the purposes of the refuge" (603 FW 2.12.A(12)). Regarding the request to identify the interim vaccination program as a priority public use and the reminder that the USFWS must answer whether the proposed use is a priority public use, the compatibility determination was modified to note that the proposed use is not a priority public use, based on the specific meaning of priority public use in the NWRS Improvement Act (16 U.S.C. 668dd(a)(3)(C)). References to the importance of implementing the interim vaccination program to the State's wildlife management and livestock interests were not added because this does not enter into the decision of whether a use is compatible.

Responses to Comments from the Wyoming Livestock Board

WLB Comment 1:

■ The Environmental Assessment (EA) expresses concern with potential safety problems with the Strain 19 vaccine. Safety studies are ongoing through efforts of the Grater Yellowstone Interagency Brucellosis Committee (GYIBC). Strain 19 has been successfully used in the cattle industry for decades; millions of doses have been administered with no significant safety problems being identified. It is very likely that the same would be true for wildlife use.

Response: The first sentence of the comment appears to be based on the issue identified on page 6 of the EA. The following sentences of the comment are consistent with the explanation given in Chapter 4 of the EA.

WLB Comment 2:

• The EA expresses concern regarding potential adverse impacts of the Strain 19 vaccine on predators, scavengers, threatened or endangered species, or other wildlife. Non-target species studies are ongoing on the Strain 19 vaccine, but are admittedly incomplete. Field Strain Brucella Abortus is more virulent than Strain 19, yet there certainly does not seem to be much concern regarding the potential for adverse impact of field strain on the non-target species. If there is truly concern regarding Strain 19, then it is past time to be concerned about the potential effects of field strain B. abortus and truly work to clean it up.

Response: The first sentence of the comment appears to be based on the issue identified on page 7 of the EA. Chapter 4 of the EA noted that there would be no adverse effects and, at most, negligible effects of Strain 19 on predators, scavengers, threatened, and endangered species.

WLB Comment 3:

■ The EA expresses concern that the use of Strain 19 vaccine could confound the results of serologic testing. This has been addressed and eliminated by the use of the cELISA test, which can differentiate between field strain and vaccine strain B, abortus.

Response: The first sentence of the comment appears to be based on the issue identified on page 7 of the EA. The second sentence of the comment is consistent with the explanation given on page 49 of the EA.

WLB Comment 4:

The question is posed regarding the efficacy of Strain 19 vaccine in elk. Efficacy studies are ongoing and although the results are not final, it appears that the vaccine is somewhere between 10 and 30 percent efficacious. No vaccine is 100 percent efficacious, and we need to consider that any reduction in infection and/or abortion in elk will lead to less transmission of the disease in elk and thereby less potential for transmission from wildlife to livestock. We need to start vaccinating now with the tools we have available and continue to develop better vaccines and delivery methods.

Response: Comment noted.

WLB Comment 5:

The EA states that the risk of transmission of Brucellosis from elk to livestock is small, but it is a concern that must be addressed because of the potential impacts to the State of Wyoming. This is a true statement. There is a concern among other states regarding the risk of Brucellosis transmission to cause reluctance in those states to purchase Wyoming cattle. This creates a very real marketability issue and thereby and economic issue. Implementing the vaccination program on the National Elk Refuge (NER) would be an indication to other states that Wyoming is continuing efforts to control and eradicate Brucellosis and minimize the risks of transmission.

Response: Comment noted.

WLB Comment 6:

I expect that there will be legal challenges to this proposal. Any legal challenge should be vigorously defended against by state and federal attorneys to uphold the legal settlement agreement between the United States and the State of Wyoming.

Response: Comment noted.